REMARKS

Applicants respectfully request reconsideration of the subject matter identified in caption, pursuant to and consistent with 37 C.F.R. §1.116, and in light of the remarks which follow.

Claims 6-16 stand rejected under 35 U.S.C. §102(b) based upon alleged public use or sale of the invention. Applicants traverse the rejection. The rejection fails to make the requisite showing that the invention was in public use or on sale in this country more than one year prior to the date of the application for patent in the United States.

The rejection alleges that certain clinical studies referenced in Blanco et al., J. Rheumatology, 31, 2082-2085, Oct. 2004, show that treatment of subjects with AAT deficiency began in 1984, and the treatment of fibromyalgia with AAT has been public knowledge since 1992 (e.g., the patients, doctors, and others involved in the clinical study). This mischaracterizes the J. Rheumatology reference.

The rejection also asserts that the inclusion of the patients in the registries (AAT Deficiency and AIR, hereinafter "Registries") constitutes a public use or disclosure; and, because the Registries were accessible within the U.S., information contained within the Registries was known within the U.S. more than one year prior to applicant's filing date. This assertion is unsupported and mischaracterizes the information presented in the Registries.

The Outstanding Rejection is Improper and Inadequate

A proper §102(b) rejection must be based upon the best available prior art (MPEP §706.02(l)); and the relied-upon prior art must teach every aspect of the

claimed invention either explicitly or impliedly (MPEP §706.02(IV)). The outstanding §102(b) rejection satisfies neither requirement.

The Registries Are Not a Publication of "the Invention"

The J. Rheumatology reference states that the two subjects (sisters) were "enlisted in the Spanish AAT Deficiency Registry, and later in the $Alpha_1$ International Registry." The J. Rheumatology reference does not state or suggest that the enlistment of those subjects in the Registries teaches or suggests that they presented with fibromyalgia (FM), that they were administered AAT, or that the AAT administration had any effect on FM. Moreover, enlistment in the Registries is anonymous, and so the identities of the subjects could not have been determined from any publicly available information from the Registries.

The J. Rheumatology reference acknowledges only that the two subjects were enlisted in Registries compiling subjects having AAT deficiency, and that they were identified as presenting with a specific genotype (PI*Z genotype). However, as the rejection expressly acknowledges, the J. Rheumatology reference is not the basis for the rejection. *Official Action, Dec. 15, 2006, p. 2.*

The rejection instead asserts that the claimed invention was in public use in this country because it was known to those involved with the Spanish AAT Deficiency Registry and Alpha1 International Registry (AIR), and because information from those Registries is presented on the world wide web, and would have been accessible to people in this country. However, there is no citation to either of those Registries showing that the claimed invention was taught or suggested in any publicly accessible portion of either of those Registries at the

appropriate time, i.e., more than one year prior to applicant's date of application for patent in the US.

The only document relied upon in support of those assertions is a printout from the AIR Website, printed Aug. 18, 2006, which cannot be relied upon as prior art. Any reliance on the printout from the AIR website is improper.

Aside from its unavailability as a prior art document, the AIR printout fails entirely to teach every aspect of the claimed invention either explicitly or impliedly. The printout from the website does not mention any aspect of the claimed invention, or anyone involved in it.

Instead, the printout supports applicant's contention that the listing of the subjects in the AIR Registry is irrelevant and insignificant. The cited document states:

> AIR members are actively studying ways to improve detection of the disease [AAT deficiency], ways to follow the course of the **lung disease**, and ways to improve treatment of the disease.
>
> AIR wants to facilitate clinical trials with innovative compounds being developed by pharmaceutical industry for diseases associated with Alpha 1 - antitrypsin deficiency, **such as emphysema, COPD and liver cirrhosis**. (emphasis added)

To the extent that the printout is relevant at all, it shows nothing more than the existence of a Registry desirous of facilitating clinical trials for treatment of AAT deficiency. It does not profess to report the results of clinical trials, nor does the printout itself contain anything resembling results of such trials. Moreover, it does not even profess to facilitate the treatment of other maladies, such as FM. Thus, the AIR was created with the intention of compiling subjects with AAT deficiency to facilitate clinical trials with the objective of improving treatment regimens for conditions typically associated with that specific disease.

The AIR and the Spanish AAT Registries list subjects only anonymously, and do not identify treatment regimens, nor do they correlate any treatment regimen with particular subjects. The Registries do not disclose the nature of any alternative treatment, nor treatment of any other condition a registered patient might present. There is nothing in the outstanding rejection to suggest otherwise.

Further, there is nothing in the J. Rheumatology reference teaching or suggesting that the Registries disclosed: 1) the identity of either of the subjects; 2) that either of the subjects also suffered from FM; 3) that AAT deficiency has any relationship with FM; 4) that AAT might be used in a treatment protocol for FM; or 5) that such treatment protocol actually had any therapeutic effect. The relied upon printout from the AIR is likewise silent as to such information.

There has been no showing that either of the referenced Registries constitutes a prior art publication of the invention; nor is there any showing that any aspect of the invention was in fact publicly accessible before the critical date.

The rejection instead relies upon unsupported inferences and assumptions about the content of the Registries, and relies only upon a statement that certain individuals were enlisted, albeit anonymously, in certain AAT Registries. Nowhere is there any citation to the Registries themselves, nor is there even a citation to a modern day (non-prior art) excerpt of either of the Registries showing <u>any</u> aspect of the claimed invention. Indeed, there is no showing that any aspect of the invention is taught anywhere in any prior art publication at the relevant time.

Applicant's statement within the J. Rheumatology reference is far from a showing or admission that every aspect (or any aspect) of the invention is disclosed in a prior art publication or was in public use in this country at the relevant time. Without such a showing, the inclusion of the subjects in one or both of the Registries

is without relevance and cannot support the §102(b) rejection. Accordingly, there has been no showing that the invention was in public use in this country more than one year prior to applicant's filing date.

Applicant's Clinical Studies Do Not Constitute Public Use in This Country

The rejection of the pending claims alleging impermissible public use is also misplaced. Such public use must occur *within this country*. MPEP §706.02(c) ("The language 'in this country' means in the United States only....").

The clinical studies referred to in the J. Rheumatology reference were carried out exclusively in Spain within a hospital of the Governmental Spanish Health Insurance System. The two subjects (sisters) were residents of Spain, were diagnosed and continually treated exclusively in that hospital, and such treatment was exclusively under the direct supervision and control of the inventor.

As discussed above, there is nothing in the J. Rheumatology reference, nor within either of the Registries, indicating that the invention was published or in public use *in this country* more than one year prior to applicant's filing date. All clinical studies and related acts were performed exclusively in Spain. Neither applicant's statements nor anything cited from either of the Registries supports an assertion that the invention was in public use in this country more than one year prior to applicant's date of application for patent in the US. Accordingly, there is no support for such an assertion, and the rejection is improper and should be withdrawn.

Conclusion

Applicant respectfully submits that the claims are now in condition for allowance, and requests formal notification to that effect. If the Examiner perceives

any impediments to such formal notification of allowance, Applicant encourages the Examiner to call his representative at the number provided below. Such informal communication with expedite examination and disposal of the application.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: February 28, 2007

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